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510(k) SUMMARY

DATE: November 17, 2006

SUBMITTER:
Innovative Spinal Technologies, Inc.
111 Forbes Blvd.
Mansfield, MA 02048
Telephone: 508/452-3520
Fax: 508/452-3600

CONTACT PERSON: Gina Yeh

TRADE NAME: Paramount™ Vertebral Body Replacement System

FDA CLASSIFICATION/ CODE: 888. 3060, MQP

DEVICE DESCRIPTION: The Paramount™ VBR device is a single piece device that may be implanted singly or in pairs. All devices are made of PEEK-Optima®. The implant is offered in various widths, heights, angles and lengths to meet individual patient anatomy. The system implants are provided sterile and the instruments are provided clean and non-sterile for steam sterilization at the user's facility.

INTENDED USE: The Paramount™ VBR is indicated for use for partial replacement of a collapsed, damaged or unstable vertebral body due to tumor or trauma / fracture to achieve decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Paramount™ VBR may be used singly or in pairs in the thoracolumbar spine (T1 to L5) with or without supplemental fixation, such as the Paramount™ Pedicle Screw System.

PREDICATE DEVICES: Spinal Concepts Inc. TRAXIS™ (K033517), Pioneer® Vertebral Spacer (K043206), and SpineVision Spacevision™ Cage (K042930).

PERFORMANCE DATA: The mechanical test results based on ASTM F2077, ASTM F2267, and ASTM F-04.25.02.02 demonstrate that the Paramount™ VBR device can be expected to perform in a manner substantially equivalent to the predicate devices. In addition, biocompatibility of the device was demonstrated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Innovative Spinal Technologies, Inc.
% Ms. Gina Yeh
Program Manager, Regulatory Affairs
111 Forbes Boulevard
Mansfield, Massachusetts 02048

JAN 12 2007

Re: K062759
Trade/Device Name: Paramount™ VBR System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: December 22, 2006
Received: December 26, 2006

Dear Ms. Yeh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0210 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use Statement

510(k) Number: K062759

Device Name: Paramount™ VBR System

Indications:

The Paramount™ VBR is indicated for use for partial replacement of a collapsed, damaged or unstable vertebral body due to tumor or trauma / fracture to achieve decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Paramount™ VBR may be used singly or in pairs in the thoracolumbar spine (T1 to L5) with or without supplemental fixation, such as the Paramount™ Pedicle Screw System.

Prescription Use ___X___ (21 CFR 801 Subpart D) or Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062759